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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/341,821
Filing Date: September 01, 1999
Appellant(s): WARING ET AL.

John M. Kilcoyne
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 07, 2005.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. The amendment after final rejection filed on 10/04/2004 has been entered.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-6, 8-10, 13-15, 17-20 do not stand or fall together. Claims 1-4, 13 and 17 stand or fall together; claims 5, 6, 10, 14, 15, and 18 stand or fall together; and claims 8, 9, 19 and 20 stand or fall together. However, the appellant's brief does not include reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

3,976,223	JASS et al.	8-1976
5,059,187	SPERRY et al.	10-1991
EP 666081	BRISTOL MYERS SQUIBB COMPANY	8-1994

(10) Grounds of Rejection and Response to Argument

The following ground(s) of rejection are applicable to the appealed claims:

(A) Claims 1-4, 13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,976,223 ('223).

The instant claim 1 reads on an aerosol container containing gel. Instant claim 13 reads on treating wound by discharging onto the wound a gel from an aerosol container. The dependent claims 2-4 and 17 recite the gel comprising hydrocolloid (claims 2 and 17), gelling agent (claim 3) and glycol (claim 4).

US '223 disclosed an aerosol container containing gel, which reads on claim 1, and comprising carboxymethyl cellulose, gelling agent and alginate, which reads on claims 2, 3 and 17. The gel comprises polyethylene glycol, which reads on claim 4 (col.6, lines 28-31, 34, 48, 63-65; col.7, lines 29-30; col.9, lines 20-23, 45-48, 51-55). The aerosol containing gel used to treat burns, which reads on claim 13 (col.9, lines 20-55). The aerosol is provided by mechanical stream break up features, i.e. self-sealing (col.2, lines 65-67). The aerosol disclosed by the reference is not a single dose container as implied by the effort made to avoid contamination of the contents during use. The limitations of claims 1-4, 13 and 17 are met by US '223.

Response to Arguments

Appellants' arguments filed 02/07/2005 have been fully considered but they are not persuasive.

However, the purpose of the package of Jass et al. is to separately store a plurality of flowable substances in a single package from which such substances may be dispensed. According to Jass et al., only the lower chamber of the outer container is pressurized with a gas through a self-sealing plug in the container bottom. See, e.g., column 2, lines 53-57. The container in Jass et al. is not self-sealing as required in the rejected claims. With respect to some implication read into Jass et al., appellants submit that Jass et al. does not address the avoidance of contamination during use. Rather, the avoidance of contamination appears to be with respect to storage. See, e.g., column 5, lines 23-32 and column 6, lines 8-13.

In response to the above argument, the examiner position is the rejected claims are directed to an aerosol container containing gel and method of treating wound comprising using the aerosol, and the cited reference teaches an aerosol containing gel for treating wound. The flowable substances that are stored separately are mixed before dispersed, therefore forming the gel, see for instant col.6, lines 39-44. In absence of reciting the aerosol vessel and where is the self-sealing barrier, the disclosure of the reference reads on self-sealing aerosol. Jass et al. disclosed at col.4, lines 52-56 that a metered amount of the flowable is delivered out of the container as spray, and that

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implies the multiple doses in the container. The cut off of the flow as well as the self-sealing properties of the aerosol inherently prevent contamination of the content of the aerosol. In any event, avoidance of contamination during use is not recited in the claims rejected under 102 rejection. Further, regarding the structure of the aerosol disclosed by the reference with only the lower part pressurized, this feature is not a distinguishing feature and not excluded by the broad language of the claims.

(B) Claims 5, 6, 10, 14, 15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '223 in view of EP 666 081 ('081).

The teaching of US '223 are disclosed under 102 rejection above.

US '223 does not teach the same composition of the gel as claimed in claim 5. The reference does not teach the gel is sterile as claimed in claims 6, 10 and 15 or the viscosity of the gel as claimed in claim 18. The reference does not teach the wound to be treated is a sinus wound as claimed in claim 14.

No superior and unexpected results of record to show the criticality in treating of sinus wound using the instant composition.

EP '081 teaches gel wound dressing comprising material comprising:

- a) from about 0.05% to 10% by weight of natural gelling agent;
- b) from about 1.0% to 10% by weight of hydrocolloid;
- c) from about 5.0% to 30.0% by weight of an alkylene glycol and
- d) at least 50% by weight of water.

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The above ingredients read on claim 5. The wound dressing is packaged and sterilized, which reads on claims 6, 10 and 15. The gel composition of the reference can be extruded in the form of gel through a nozzle (page 2, lines 20-24; page 3, lines 14-18). The gel of the reference has viscosity of 50-800 Pas, which reads on claim 18, (page 2, lines 54-55). The reference disclosed the gel conforms readily to the shape of the wound particularly when the wound includes a cavity, and that teaching suggests treating sinus wound (page 2, lines 8-9).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver an aerosol containing gel wound dressing as disclosed by US '223, and replace the gel by the sterile gel composition disclosed by EP '081, motivated by the teaching of EP '081 that the gel composition has a viscosity that reduces the flow of the gel from the wound site and conforms readily to the shape of the wound particularly when the wound includes a cavity, with reasonable expectation of the delivered aerosol containing gel to treat wounds, and in particular sinus wounds with success.

Response to Arguments

Appellants' arguments filed 02/07/2005 have been fully considered but they are not persuasive.

Appellants traverse the rejection of claims 5, 6, 10, 14, 15 and 18 under USC 103 as being unpatentable over Jass et al. in view of EP 666 081 ('081) by arguing that the invention is not simply substituting one liquid in any aerosol device for another. The

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focus of the invention in Jass et al. is to separately store a plurality of flowable substances in a single package from which such substances may be dispensed. Since that is the focus of the invention, there is no reason other than hindsight to substitute the composition of the '081 document for the composition of Jass et al. Further, while the composition in the '081 document is a gel, the '081 document does not provide that which is missing in Jass et al. as noted above. The storage of plurality of flowable substances in a single package is a distinguishing feature of Jass et al. from the present invention.

In response to these arguments, the examiner position is that Jass et al. teach gel composition comprising glycol, gelling agent, carboxymethyl cellulose and water (col.6, lines 62-65; col.7, lines1-15, 30). However, Jass does not teach the amount of the ingredients. EP '081 is relied upon for teaching the amounts of the ingredients of the wound dressing gel composition and its viscosity. It is appropriate to rely on EP '081 and combine it with the teachings of Jass since both references are in the field of applicant's endeavor and both are reasonably pertinent to the particular problem with which the applicant was concerned, which is wound dressing. The gel composition disclosed by Jass is used as bandage for burns and EP '081 teaches gel for treating wounds, as appellants admit, therefore, it is obvious to deliver the gel composition of the EP '081 in the aerosol of Jass because that EP '081 teaches the gel composition conforms readily to the shape of the wound particularly when the wound is a cavity and it can be delivered from a nozzle along with the low viscosity of the gel, all imply the

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suitability to aerosol delivery. Hence the rejection is not based on hindsight reasoning as appellants assert. In any event, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The storage of plurality of flowable substances in a single package is not a distinguishing feature of Jass et al. from the present invention because the plurality of substances are mixed before delivery and gel is delivered from the aerosol of Jass.

(C) Claims 8, 9, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,059,187 ('187) in view of US '223.

US '187 teaches a method for providing an aerosol container and method for cleaning the wound including the steps of introducing the wound cleaning material through an opening into a pouch and then the opening is closed by a valve, the container is then sterilized and the propellant is introduced into the can (abstract; col.3, lines 1-10; col.5, lines 8-21).

US '187 does not teach the aerosol vessel containing gel.

The teachings of US '223 are discussed under 102 rejection above, an aerosol containing wound treating gel.

Accordingly, it would have been obvious for one having ordinary skill in the art at the time of the invention to provide an aerosol for wound treating produced by the method disclosed by US '187, and replace its contents by wound-treating gel as disclosed by US '223, motivated by the teaching of US '223 that gel provides a soothing strippable gel bandage that excludes air, with reasonable expectation of the delivered aerosol containing gel to treat wound with success.

Response to Arguments

Appellants' arguments filed 02/07/2005 have been fully considered but they are not persuasive.

Appellants traverse the rejection of claims 8, 9, 19 and 20 under USC 103 as being unpatentable over US Patent No. 5,059,187 ("Sperry et al.") in view of Jass et al. by arguing that Sperry et al. teach away from the present invention in at least two important ways. First, Sperry et al. do not teach or suggest a dispensing vehicle that contains multiple doses of wound-treating material. Instead, Sperry et al. teach the container contains enough wound cleaning solution to irrigate the average wound or abrasion. Thus, nothing in Sperry et al. suggests a wound gel dispenser capable of dispensing multiple doses while keeping the wound gel contents reasonably free of contaminants. A second way in which Sperry et al. teach away from the present invention is in the fact that Sperry et al. disclose a method of dispensing liquid, not gel, to a wound. This method lacks the complicating factors of dispensing a gel that is in gel-

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form within the container. Further, Sperry et al. do not make up for the deficiencies of Jass et al. as noted above.

In response to the first appellant's argument, that Sperry et al. do not teach the multiple doses of the wound treating material, the examiner position is that the reference is relied upon solely for the teaching of the method of making and sterilizing an aerosol. The rejected claims 8 and 9 are directed to method of making an aerosol, and Sperry's reference teaches the claimed method of making an aerosol. The reference further teaches sterile content of the aerosol which is not contaminated at use, as desired by applicant. Regarding the second applicants' argument that the reference teaches dispensing liquid and not gel, the examiner position is that the reference is relied solely upon for teaching the method of making of the aerosol vessel, and one cannot show nonobviousness by attacking the references individually where the rejections are based on combination of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, the rationale to modify the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art and the reason to modify the reference may often suggest what the applicant has done. Thus, the secondary reference does not need to teach the gel that is taught by the primary reference.

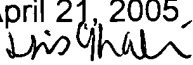
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(D) Objection to the Specification

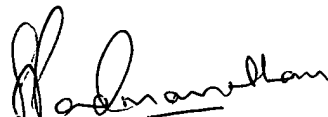
With regard to the objections previously made to the specification, the objections are maintained because appellants have not argued or responded by making the suggested objections to insert headings for the application sections as required by guideline provided by 37 CFR 1.77(b).

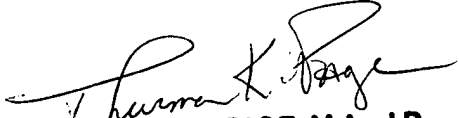
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Isis Ghali
Examiner
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IG
April 21, 2005

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